

OCT - 2 2000

K000003

Summary of Safety and Effectiveness Information Premarket Notification Section 510(k)	Tornier Total Elbow Prosthesis
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September 11, 2000

Manufacturer/Contact Person:

TORNIER, S.A.
Rue du Doyen Gosse
38330 SAINT-ISMIEU France
Registration No : 9610667
Ms. Anne LE ROUZO
Regulatory Affairs & Quality Manager

Official Correspondent (USA):

Mr. David W. SCHLERF
BUCKMAN Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389
925.356.2640

Classification Name(s):

~ 888.3160: Elbow joint metal/polymer semi-constrained cemented prosthesis. (a) Identification. An elbow joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace an elbow joint. The device limits *translation* and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a humeral resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a radial resurfacing component made of ultra- high molecular weight polyethylene. This generic type of device is limited to those prostheses intended for use with bone cement (Sec.888.3027). (b) Classification. Class II.(c) Code : 87JBD.

888.3150: Elbow joint metal/metal or metal polymer constrained cemented prosthesis. (a) Identification. An elbow joint metal/metal or metal/polymer constrained cemented prosthesis is a device intended to be implanted made exclusively of alloys, such as cobalt-chromium- molybdenum, or made from these alloys with a ultra-high molecular weight polyethylene bushing, and used to replace an elbow joint. The device prevents dislocation in more than one anatomic plane and consists of two components which are Linked together. This generic type of device is limited to those prostheses intended for use with bone cement (Sec. ~888.3027). (b) Classification. Class III. (c) Date PMA or notice of completion of a PDP is required. No effective date has been established of the requirement for premarket approval. See Sec. 888.3. (d) Code: 87JDC

Device Description:

Overview. Total elbow replacement are used to treat a number of clinical conditions such are severe pain or significant disability in degenerative, rheumatoid or traumatic disease of the elbow joint. It is also used in revision procedures where other treatments or devices have failed and treatment of fractures that are unmanageable using other techniques. The usual goal of such surgery is to restore the elbow joint to its best working condition and to reduce or eliminate pain. The Tornier Total Elbow Prosthesis is intended to accomplish these goals. The Tornier elbow prosthesis is intended for use as a cemented total elbow. Device description. The *Tornier Total Elbow* prosthesis is a 3-part system consisting of a humeral stem, a ulnar component and a radial head. The humeral stems are offered in cobalt- chrome alloy. The ulnar and radial components are produced from cobalt-chrome alloy and ultra high molecular weight polyethylene.

Three sizes are available. The sizes combination between the humeral and the ulnar component does not allow interchangeability. For example, selecting the small size of the humeral component imposes to select the small size of the ulnar component.

Materials. Humeral implant components are available in CoCr chromium-cobalt alloy according to standard ISO 5832-7 or standard ISO 5832-4. The ulnar and radial components are made of CoCr chromium-cobalt alloy according to standard ISO 5832-7 or standard ISO 5832-4, and UHMWPE ultra high molecular weight polyethylene according to standard ISO 5834-2.

Indications. The *Tomier Elbow Prosthesis* is intended for total elbow arthroplasty. Prosthetic replacement with this device may be indicated in the following cases: to relieve severe pain or significant disability in degenerative, rheumatoid, or traumatic disease of the elbow joint; correction of *functional* deformities; revision procedures where other treatments or devices have failed; treatment of fractures that are *unmanageable* using other techniques.

Contraindications and Cautions. Only surgeons fully experienced in total arthroplasty surgical technique of the elbow should use the device. Please contact Tomier about available instructional course demonstrations and bio-skills workshops.

Packaging and Sterilization Information:

The prostheses are supplied sterile from Tomier. The technique used to achieve the sterilization is known as gamma radiation sterilization. A radiation dose of at least 2.5 Mrad is utilized. The sterility assurance level (SAL) is 10^{-6} . The validation of the sterilization has been carried out according to the standard EN552. Once the packaging is opened, the *implant* must never be resterilized. In case of packaging is damaged, the implant must be rejected.

The instruments required to properly use the device are provided non-sterile. They must be decontaminated, cleaned and sterilized prior to each surgery. All packaging, labeling and shipping materials must be removed from the instruments prior any operation. The recommended sterilization method is steam sterilization at 274 F for 15 minutes.

Equivalent / Predicate Device(s):

Coonrad / Morrey Total Elbow, Zimmer, K 973357
Sorbie - Quester Elbow System, Wright, K 955099



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT - 2 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. David W. Schlerf
Buckman Company
200 Gregory Lane
Suite C-100
Pleasant Hill, California 94523-3389

Re: K000003
Trade Name: Tornier Total Elbow Prosthesis
Regulatory Class: III
Product Code: JDC and JDB
Dated: July 7, 2000
Received: July 21, 2000

Dear Mr. Schlerf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

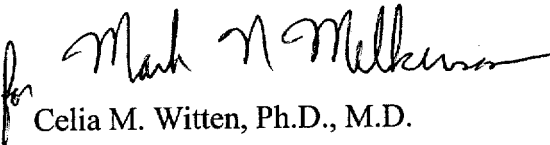
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 - Mr. David W. Schlerf

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and
Neurological Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

510(k) Number: **K000003**

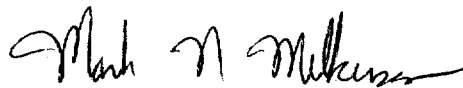
Device Name: **Tornier® Total Elbow Prosthesis**

Indications For Use:

- Prosthetic replacement of the elbow joint.
- Severe pain & significant disability due to degenerative, rheumatoid, or traumatic diseases of the elbow joint.
- Correction of functional deformities; revision procedures where previous treatments or implants have failed.
- Treatment of elbow fractures unmanageable by other techniques.
- This device is intended for use with bone cement.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K000003

Prescription Use yes
(Per 21 CFR 801.109)

OR

Over-The-Counter Use no
(Optional format 1-2-96)